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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,342	01/31/2001	John T. McDevitt	5119-00523/EBM	7210

7590 02/14/2003

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EXAMINER	
DO, PENSEE T	
ART UNIT	PAPER NUMBER
1641	11

DATE MAILED: 02/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/775,342	MCDEVITT ET AL.	
	Examiner	Art Unit	
	Pensee T. Do	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *309-327 and 356* is/are pending in the application.

4a) Of the above claim(s) *327 and 356* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *309-326* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6& 8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of group I, claims 309-326 in Paper No. 10 is acknowledged.

Claim 356 is categorized with claim 327 (group II). Thus, claim 356 is non-elected.

Claim Status

Claims 309-327, 356 are pending. Claims 327 and 356 are non-elected.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 309-326 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particles with magnetic susceptibility, does not reasonably provide enablement for particles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working

examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention: - the instant invention is directed to a method for forming a sensor array configured to detect an analyte in a fluid comprising forming a cavity in a supporting member; applying a magnetic field to the cavity; passing a particle over the cavity wherein the particle is configured to produce a signal when interacts with the analyte; and wherein the particle is configured to interact with the magnetic field such that movement of the particle is inhibited by the applied magnetic field.

The state of the art: - the prior art teaches that magnetic particles or magnetic responsive particles are used to capture target molecules in a well under the influence of a magnetic field.

The predictability or lack thereof in the art:- in view of the lack of teachings in the prior art that show or suggests that non-magnetic responsive particles can be used to capture target molecules in a well, which is being, applied a magnetic field.

The amount of direction or guidance present: - the instant specification fails to provide guidance on how to use non-magnetic responsive particles or non-magnetic particles for capturing target molecules using a magnetic force.

The presence or absence of working examples:- there is no examples in the specification that show non-magnetic responsive particles can capture target analyte using just the magnetic force, i.e. magnetic field.

The quantity of experimentation necessary: - it would require an undue amount of experimentation for a skilled artisan to make and use the invention as claimed.

The relative skill of those in the art: The level of skill in the art is high.

The breadth of the claims:- the claimed method is drawn to using a magnetic field to capture magnetic particles bound target analytes in a cavity.

The instant invention is not enable for using a magnetic field to capture all the particles including non-magnetic responsive particles on a substrate.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 309-326 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 309 is confusing. The preamble of claim 309 recites that a method for forming a sensor "array", but the body of the claim fails to recite an sensor array formed. There is only one particle and one cavity. How can there be an "array" of sensor? Furthermore, the claim is unclear of what the sensor is, i.e. the particle? The cavity and the particle? Or the captured particle on the cavity?

Claim 325 is confusing because in claim 309, the particles are inhibited from movement when being passed through the cavity that is applied a magnetic field. But claim 325 recites that placing the polymeric material and magnetic material in a solvent; and applying ultrasound to the solvent. Since the method of claim 325 fails to recite the sequential order of its steps, it is assumed that these steps are performed after the steps of claim 309. Thus, it is confusing because how are the polymeric/magnetic

particles to be moved after they are inhibited from movement by the magnetic field? What is the role of the solvent in this method? And of the ultrasound?

Claim 326 is also confusing because it is unclear whether claim 326 is another embodiment of the invention or the steps of the method of claim 326 are sequential to the steps of the method of claim 309.

Claim 326, please also insert –the—before "cavities" in line 3 for proper antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 309, 312-314, 326 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatch et al. (US 6,514,415) further in view of Wang et al. (US 5,922,617).

Hatch teaches a method and apparatus for magnetic separation of particles within a container (cavity). The container can be 96-well micro plates (supporting member), 1536 well micro-plates; tubes, petri dishes. (see col. 3, lines 37-42). The container contains a number of particles and a number of magnetically susceptible particles. A number of magnets are arranged in a plane and is placed close to the container. The magnetic poles of the magnets are arranged in a pattern to apply magnetic fields oriented perpendicular to the plane on the container. The pole pattern

provides in consistent separation across the container of the number of magnetic susceptible particles from the rest of the particles. The magnets may be ferromagnetic, ferromagnetic, alinco, polymer-bonded , rare earth and ceramic materials. The magnets can be proximate the container such as at the bottom of the container or the side of the container. The paramagnetic micro-beads are coated with a chemical specific substance that will bind with the target particles. The application of the magnetic field from the magnets proximate the container attracts the microbeads with the bonded target particles towards the magnets of the container and the target particles are separated from the unwanted particles within the solution. The magnets comprise of permanent magnets and electromagnets. (col. 5, lines 32-40).

However, Hatch fails to teach that the particles (magnetic particles) are configured to produce a signal when the particles interact with the analyte/target particle.

Wang teaches different methods of immunoassay using a particle such as magnetic particles. In one embodiment the particle provides a positive singal (col. 7, lines 1-20). The particle has bound components such as a receptor and is encoded with a binary code of a homologous aliphatic sequence with halides (indicator), which is releasable from the particle. The method involves isolating the particle, photolysing the coded molecule and analyzing the bound component. In another embodiment, the particles are labeled and using one or more labeled proteins of interest, one can detect which of the compounds of the library bind to the protein of interest (col 7, ln. 60-67). Regarding the limitation of claim 313, since Hatch and Wang both teach using an

electromagnetic to hold the particles in place (col. 6, lines 5-15), it is obvious to one of ordinary skills in the art to apply an electric current to the electromagnet in order to produce an electromagnetic field.

It would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the array of Hatch by placing the particles taught by Wang into the wells of the array because Wang teaches that particles such as magnetic beads offer the advantages of providing a great flexibility, where the bound components can be arrayed in numbers of sizes and with the beads, the arrays are reversible and can be retrieved for further processing (see col. 6, lines 63-67). The use of arrays containing particles offers the advantage of greater surface area for a reaction and the ability to screen multiplicity of chemical compounds simultaneously.

Claims 309, 312, 313, 314, 326 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (US 6,103,479) in view of Wang et al. (US 5,922,617).

Taylor teaches a device with non-uniform micro-patterned array of cells and method for making the device (col. 6, lines 40-50). In one embodiment of the chamber (ref. # 12) (support member) has channels and matching etched domains (ref. #13) (cavity). The non-uniform micro-patterned array of cells is inverted so that that the wells become submerged in the etched domains filled with fluid (col. 14, lines 48-54, figs. 4 and 7). The etched domains are larger in diameter than the wells of the non-uniform micro-patterned array of cells. The microfluidic channels are etched into each row of etched domains of the chamber. Each row of connected channels can be filled simultaneously or sequentially. During filling of the channel by valves and pumps or

capillary action, each of the channels of the chamber fills each etched domain in the row of etched domains connected by the channel. The base of the non-uniform micro-patterned array of cells can be glass, plastic, or silicon wafer (col. 8, lines 34-40).

However, Taylor fails to teach the use of particles it its array.

Wang teaches different methods of immunoassay using a particle such as magnetic particles. In one embodiment the particle provides a positive singal (col. 7, lines 1-20). The particle has bound components such as a receptor and is encoded with a binary code of a homologous aliphatic sequence with halides (indicator), which is releasable from the particle. The method involves isolating the particle, photolysing the coded molecule and analyzing the bound component. In another embodiment, the particles are labeled and using one or more labeled proteins of interest, one can detect which of the compounds of the library bind to the protein of interest (col. 7, ln. 60-67).

It would have been obvious to one of ordinary skills in the art at the time the invention was made to modify the array of Taylor by placing the particles taught by Wang into the wells of the array because Wang teaches that particles such as magnetic beads offer the advantages of providing a great flexibility, where the bound components can be arrayed in numbers of sizes and with the beads, the arrays are reversible and can be retrieved for further processing (see col. 6, lines 63-67). The use of arrays containing particles offers the advantage of greater surface area for a reaction and the ability to screen multiplicity of chemical compounds simultaneously. Regarding the limitation of claim 313, since Wang teaches using an electromagnetic to hold the particles in place (col. 6, lines 5-15), it is obvious to one of ordinary skills in the art to

apply an electric current to the electromagnet in order to produce an electromagnetic field.

Claims 310, 311 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor (US 6,103,479) in view of Wang (US 5,922,617) further in view of Kroy (US 5,252,294).

Taylor and Wang have been discussed above.

However, Taylor and Wang fail to teach a cavity is formed by anisotropic etching method and the sidewalls are tapered at an angle.

Kroy teaches a method of forming the cavity by anisotropic etching method and the sidewalls of the cavity are tapered at an angle (col. 2, lines 47-58). The sidewalls are tapered at an angle of 54.7 degrees. This method of etching would provide the advantage of depressions with high geometric precision and very narrow tolerances.

It would have been obvious to one of ordinary skills in the art to include the method of forming the cavity by anisotropic etching method and the sidewalls are tapered at an angle taught by Kroy to the array of Taylor as modified by Wang for the advantage of providing depressions of the cavity with high geometric precision and very narrow tolerances (Kroy col. 2, lines 47-52).

Claims 315, 317, 322, 323 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor modified by Wang further in view of Owen et al. (US 5,866,099).

Taylor and Wang have been discussed above.

However, Taylor and Wang fail to teach that the particle comprises a polymeric material and a ferromagnetic material or a ferrite magnetic material, or iron oxide magnetic material.

Owen teaches a magnetic-polymer particle, useful in immunoassay techniques and various other biological/medical applications. The magnetic material comprises ferromagnetic or iron oxide or ferrite. The magnetic-polymer particles exhibit many different useful properties. These particles are magnetic due to the inclusion of a form of magnetic metal compound (e.g. iron similar in the form to magnetite, or a similar compound). The particles can be formulated to be resuspendable after aggregation and to produce relatively stable suspensions, which do not settle even after several days of quiescent storage. Furthermore, the particles can be relative small and therefore filter sterilizable. Finally, these particles can be tailored-made to include specific biofunctional ligands useful in various analytical, diagnostic and other biological/medical applications (see col. 3, lines 24-59).

It would have been obvious to one of ordinary skills in the art to be motivated to use the polymeric particles with magnetic material such as ferrite, iron oxide or ferromagnetic as taught by Owen in the modified method of Taylor and Wang because these particles exhibit many useful properties such as they can be resuspendable after aggregation to produce stable suspension, are filter sterilizable, and the polymeric composition is useful in that it provides specific biofunctional groups for specific ligands useful in various analytical, diagnostic and other biological/medical applications. (see col. 3, lines 24-59). Furthermore, the particles of Owen offer the advantages of

providing high porosity microbeads that can be used as an absorbent material and as a solid support in a variety of biological/medical applications.

Remarks

Claims 316, 318-321, 324, 325 are free of prior arts.

The prior arts fail to teach particles comprising a polymeric material and one of the of the followings: an alnico magnetic material, barium ferrite magnetic material, strontium ferrite magnetic material, neodymium iron boron magnetic material, samarium cobalt magnetic material, and a metallocene and a metal hydroxide; and the method further comprises placing the polymeric material and magnetic material in a solvent; and applying ultrasound to the solvent.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pensee T. Do whose telephone number is 703-308-4398. The examiner can normally be reached on Monday-Friday, 7:00-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-746-5291 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Pensee T. Do
Patent Examiner
February 9, 2003

Christopher L. Chin

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ 1641